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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,277	06/08/2006	Friedhelm Brassel	13455/1	6606

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,277	BRASSEL, FRIEDHELM	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 have been cancelled and claims 17-29 are new. Applicant's amendments have necessitated a new ground of rejection. Accordingly, this Action is FINAL.

Withdrawn rejections:

Applicant's amendments and arguments filed 9/19/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doerfler et al. (Neuroradiology 2001, 43, 1112-1117) in view of Mottu et al. (Biomaterials, 2000, 21, 803-811).

Applicant claims a medical kit for use in a method to produce a liquid embolizate and a method for the production of a liquid embolizate.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Doerfler et al. teach Ethibloc (60% ethanolic zein) and Lipiodol compositions in ratios of E/L 1:1, 1:2 and 1:3) (Abstract and page 1113, table 1 and Ethibloc right column). Doerfler et al. teach injection through a microcatheter is not smooth because of Ethibloc's high viscosity and to decrease the viscosity by mixing with the oily contrast medium Lipiodol (page 1113, right column Ethibloc). From page 1113:

> Ethibloc (Ethicon, Norderstedt, Germany) is an ethanolic (60%) solution of 210 mg zein (corn protein)/ml ethanol, 162 mg sodium amidotrizoate/ml ethanol, 145 mg oleum papaveris/ml ethanol and 6 mg propyleneglycol/ml ethanol. As the alcohol dissolves in aqueous media, zein precipitates and forms a cast with a consistency resembling "chewing gum".
>
> Injection through a microcatheter is not smooth, because of Ethibloc's high viscosity. To decrease this high viscosity and to enhance visibility under fluoroscopy, Ethibloc can be mixed with the iodinated contrast agent Lipiodol in different solutions.

Oleum papaveris is another term for poppy seed oil. Amidotrizoate is a radiopaque agent. Methods of mixing Ethibloc in 3-way tap with Lipiodol are taught (page 1113, study design). Doerfler et al. teach that the high viscosity of Ethibloc can become a problem with certain microcatheters which rupture while the embolic agent is injected (page 1115, lower right paragraph through page 1116).

Doerfler et al. establish two things: 1) Ethibloc is highly viscous and problematic for injection and 2) Lipiodol is a known contrast medium in liquid form.

Mottu et al. teach water-miscible solvents for embolic liquids which include ethanol (Table 2, page 805).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Doerfler et al. is that Doerfler et al. do not expressly teach a kit with 3 component syringes and at least one empty syringe for accommodation of the liquid embolizate where component (a) is 20 to 80 % of an occlusion mixture; (b) is 10 to 40% of a radiopaque contrast medium in liquid form and (c) is 10 to 40% ethanol.

2. The difference between the instant application and Doerfler et al. is that Doerfler et al. do not expressly teach a method of producing a liquid embolizate with 3 components consisting of (a) is 20 to 80 % of an occlusion mixture; (b) is 10 to 40% of a radiopaque contrast medium in liquid form and (c) is 10 to 40% ethanol; wherein (a) is homogenized; (b) is admixed with (a) and (c) is then admixed to (a) and (b).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a kit with 3 component syringes and at least one empty syringe for accommodation of the liquid embolizate where component (a) is 20 to 80 % of an occlusion mixture; (b) is 10 to 40% of a radiopaque contrast medium in liquid form and (c) is 10 to 40% ethanol, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is merely common sense to dilute the known viscous solution with more solvent before admixture and injection. It is nothing more than judicious selection of materials (syringes) for the kit by one of ordinary skill in the art. Volume ratios of between 1:2 and 2:1 for components (b) and (c) and 15-35 % v/v of components (b) and (c) and 30-70 % v/v of (a) are easily obtained by optimization of the amount of solvent in the absence of evidence to the contrary. It is merely ordinary innovation to add more ethanol solvent to decrease the viscosity. The expected and predictable result is a less viscous solution of Ethibloc.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add more ethanol to the composition of Doerfler et al., as suggested by Mottu et al., to produce a liquid embolizate with 3 components consisting of (a) is 20 to 80 % of an occlusion mixture; (b) is 10 to 40% of a radiopaque contrast medium in liquid form and (c) is 10 to 40% ethanol; wherein (a) is

homogenized; (b) is admixed with (a) and (c) is then admixed to (a) and (b), and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Doerfler et al. teaches that the compositions are highly viscous and rupture certain catheters and injections are not smooth. To improve injection smoothness and decrease viscosity it is obvious to add more solvent. Ethibloc comes as an ethanolic solution. It would be obvious to add more ethanol since ethanol is the solvent and ethanol is taught as an embolic solvent by Mottu et al. Volume ratios of between 1:2 and 2:1 for components (b) and (c) and 15-35 % v/v of components (b) and (c) and 30-70 % v/v of (a) are easily obtained by optimization of the amount of solvent in the absence of evidence to the contrary. It is merely ordinary innovation to add more ethanol solvent to decrease the viscosity. The expected and predictable result is a less viscous solution of Ethibloc.

With respect to the limitations of mixing under vacuum; eliminating air by centrifuging, separate packing; drawn up in syringes and selecting aneurysms or arteriovenous short circuits these are merely selection of design choices by one of ordinary skill in the art.

From recent case law: “the results of ordinary innovation are not the subject of exclusive rights under the patent laws.” (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007) page 24).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst V Arnold
Examiner, Art Unit 1616
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/Johann R. Richter/

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